

12/11/98
jc618 U.S. PTO

Docket: 2100 CON
(203-2407 CON)

A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David Lee Gines

Serial No.: To Be Assigned Examiner: Unknown

Filed: Concurrently Herewith Group Art Unit: Unknown

For: **ELECTROSURGICAL GENERATOR WITH ADAPTIVE POWER CONTROL**

jc549 U.S. PTO
09/209323
12/11/98

APPLICATION TRANSMITTAL LETTER

Asst. Commissioner For Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the ☒ utility ☐ design patent application in this case including:

1. ☒ This application is a ☒ Continuation; ☐ Divisional ☐ Continuation in Part of prior application Serial No. 08/838,548 filed on April 9, 1997 [entire genealogy should be set forth].
2. ☐ This application claims priority from Provisional Application No. _____, filed _____.
3. ☒ The application consisting of 19 pages (including specification, claims and abstract).
4. ☒ 11 sheet(s) of drawings is enclosed. The drawings are:
 - a. ☐ formal; or
 - b. ☒ informal; formal drawings will be submitted in due course.
5. ☒ The prior application is assigned of record to Valleylab, Inc., recorded on April 9, 1997 at Reel 8505, Frame 0830.
6. ☒ The Declaration and Power of Attorney document was previously filed in the prior application serial no. 08/838,548, filed on April 9, 1997, a copy is enclosed.
6. ☒ The current power of attorney is to: JOHN C. ANDRES, Reg. No. 30,931; NEIL D. GERSHON, Reg. No. 32,225; BASAM E. NABULSI, Reg. No. 31,645; MARK FARBER, Reg. No. 34,159; NEIL Y. GILBERT, Reg. No. 35,156; and CAROLYN H. BLANKENSHIP, Reg. No. 35,449; each of them of United States Surgical Corporation, 150 Glover Avenue, Norwalk, Connecticut 06856.

PETER G. DILWORTH, Reg. No. 26,450; ROCCO S. BARRESE, Reg. No. 25,253; DAVID M. CARTER, Reg. No. 30,949; PAUL J. FARRELL, Reg. No. 33,494; PETER DELUCA, Reg. 32,978; ADRIAN T. CALDERONE, Reg. No. 31,746; GEORGE M. KAPLAN, Reg. No. 28,375; JEFFREY S. STEEN, Reg. No. 32,063; JOSEPH W. SCHMIDT, Reg. No. 36,920; RAYMOND E. FARRELL, Reg. No. 34,816; RUSSELL R. KASSNER, Reg. No. 36,183; FRANK CHAU, Reg. No. 34,136; CHRISTOPHER G. TRAINOR, Reg. No. 39,517; GEORGE LIKOUREZOS, Reg. No. 40,067; JAMES M. LOEFFLER, Reg. No. 37,873; WILLIAM E. LEWIS, Reg. No. 39,274; JOHN G. TUTUNJIAN, Reg. No. 39,405; JAMES J. BITETTO, Reg. No. 40,513; and MARK S. LEONARDO, Reg. No. 41,433, each of them of DILWORTH & BARRESE, 333 Earle Ovington Boulevard, Uniondale, New York 11553.

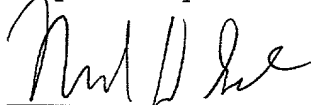
The power of attorney is of record in U.S. Application Serial No. 08/838,548 filed on April 9, 1997, a copy is enclosed.

7. [X] The Application filing fee is calculated below.

	No. Filed	No. Extra*	Rate:	Fee
Basic Fee:				\$ 790.00
Total Claims:	18 - 20 = 0		x 22.00	\$ -0-
Indep Claims:	4 - 3 = 1		x 82.00	\$ 82.00
[] Multiple Dependent Claims Presented				
				+ \$270.00
				\$ 0.00
TOTAL:				\$ 872.00

9. [X] Please charge Deposit Account No. 21-0550 in the amount of \$872.00 which includes filing fee and recordation fee).
TWO DUPLICATE COPIES OF THIS PAPER ARE ENCLOSED.
10. [X] The Commissioner is hereby authorized to charge any additional fees which may be required for this application, or credit any overpayment to Deposit Account No. 21-0550. TWO DUPLICATE COPIES OF THIS SHEET ARE ENCLOSED.

Respectfully submitted,



Neil D. Gershon
Reg. No. 32,225
Attorney for Applicant

Date: 12/11/98

United States Surgical Corp.
150 Glover Avenue
Norwalk, Connecticut 06856
(203) 845-1480

Docket: 2100 CON
(203-2407 CON)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David Lee Gines

Serial No.: To Be Assigned Examiner: Unknown

Filed: Concurrently Herewith Group Art Unit: Unknown

For: **ELECTROSURGICAL GENERATOR
WITH ADAPTIVE POWER CONTROL**

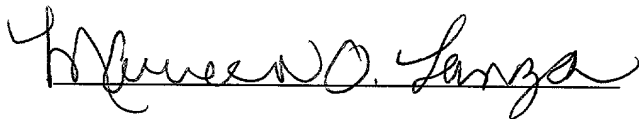
CERTIFICATE OF EXPRESS MAILING

"Express Mail" Mailing Label No.: EH979233658US
Date of Deposit: December 11, 1998

I hereby certify that the following:

- ☒ This Certificate of Express Mailing
- ☒ Request for filing a Continuation Application Transmittal letter
- ☒ A patent application consisting of 19 pages of abstract, specification and claims
- ☒ Declaration and Power of Attorney for patent application as originally filed.
- ☒ 11 sheets of [] formal [x] informal drawings
- ☒ Information Disclosure Statement
- ☒ PTO Form 1449
- ☒ Return postcard

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR Section 1.10 on the Date of Deposit indicated above in an envelope addressed to the Asst. Commissioner for Patents, Washington, D.C. 20231.



UNITED STATES SURGICAL CORPORATION
150 Glover Avenue
Norwalk, CT 06856
(203) 845-4603

ELECTROSURGICAL GENERATOR WITH ADAPTIVE POWER CONTROL

Background

This application is a Continuation of U.S. application Serial No. 08/838,548, filed on April 9, 1997, the contents of which are incorporated herein by reference.

5

Field of the Invention

The present invention relates to an electrosurgical generator with an adaptive power control, and more particularly to an electrosurgical generator that controls the output power in a manner that causes impedance of tissue to rise and fall cyclically until the tissue is completely desiccated.

10

Background of the Disclosure

Electrosurgical generators are used by surgeons to cut and coagulate tissue of a patient. High frequency electrical power is produced by the electrosurgical generator and applied to the surgical site by an electrosurgical tool. Monopolar and bipolar configurations are common in electrosurgical procedures.

15

Electrosurgical generators are typically comprised of power supply circuits, front panel interface circuits, and RF output stage circuits. Many electrical designs for electrosurgical generators are known in the field. In certain electrosurgical generator designs, the RF output stage can be adjusted to control the RMS output power. The methods of controlling the RF output stage may comprise changing the duty cycle, or changing the amplitude of the driving signal to the RF output stage. The method of controlling the RF output stage is described herein as changing an input to the RF output stage.

20

Electrosurgical techniques have been used to seal small diameter blood vessels and vascular bundles. Another application of electrosurgical energy is tissue welding. In this application, two layers of tissue are grasped and clamped together while electrosurgical power is applied. The two layers are thereby welded together. Tissue welding is similar to vessel sealing, except that a vessel or duct is not necessarily sealed in this process. For example, tissue welding may be used instead of staples for surgical anastomosis. Electrosurgical power has a desiccating effect on tissue during tissue welding or vessel sealing. As used herein, the term "electrosurgical desiccation" is meant to

30

encompass any tissue desiccation procedure, including standard electrosurgical coagulation, desiccation, vessel sealing, and tissue welding.

One of the problems associated with electrosurgical desiccation is undesirable tissue damage due to thermal effects. The tissue at the operative site is heated by the electrosurgical current. Healthy tissue adjacent to the operative site can become thermally damaged if too much heat is allowed to build up at the operative site. The heat may conduct to the adjacent tissue and cause a large region of tissue necrosis. This is known as thermal spread. The problem of thermal spread becomes important when electrosurgical tools are used in close proximity to delicate anatomical structures. Therefore, an electrosurgical generator that reduced the possibility of thermal spread would offer a better opportunity for a successful surgical outcome.

Another problem that is associated with electrosurgical desiccation is a buildup of eschar on the surgical tool. Eschar is a deposit on an electrosurgical tool that is created from tissue that is desiccated and then charred by heat. The surgical tools will often lose effectiveness when they are coated with eschar. The buildup of eschar could be reduced when less heat is developed at the operative site.

Practitioners have known that a measurement of electrical impedance of tissue is a good indication of the state of desiccation of the tissue. Several commercially available electrosurgical generators can automatically terminate output power based on a measurement of impedance. Several methods for determining the optimal point of desiccation are known in the field. One method sets a threshold impedance, and terminates power once the measured impedance of the tissue crosses the threshold. Another method terminates power based on dynamic variations in the impedance.

A discussion of the dynamic variations of impedance of tissue can be found in the article, Vallfors and Bergdahl, "Automatically Controlled Bipolar Electrocoagulation," Neurosurgical Review, 7:2-3, pp. 187-190, 1984. Figure 2 in the Vallfors article shows impedance as a function of time during heating of tissue. Vallfors reports that the impedance value of tissue proved to be close to minimal at the moment of coagulation. Based on this observation, Vallfors suggests a micro-computer technique for monitoring the minimum impedance and subsequently terminating output power to avoid charring the tissue.

A second article by Bergdahl and Vallfors, "Studies on Coagulation and the Development of an Automatic Computerized Bipolar Coagulator," Journal of Neurosurgery, 75:1, 148-151, July 1991, discusses the impedance behavior of tissue and its application to electrosurgical vessel sealing. The Bergdahl article reported that the impedance had a minimum value at the moment of coagulation. The Bergdahl article also reported that it was not possible to coagulate safely arteries with a diameter larger than 2 to 2.5 millimeters. The present invention helps to overcome this limitation by enabling electrosurgical vessel sealing of larger diameter vessels.

U.S. Patent 5,540,684 discloses a method and apparatus for electrosurgically treating tissue in a manner similar to the disclosures of Vallfors and Bergdahl. The '684 patent addresses the problem associated with turning off the RF output automatically after the tissue impedance has reached a minimum value. A storage device records maximum and minimum impedance values, and an algorithm computes an optimal time for terminating output power.

U.S. Patent 4,191,188 discloses a variable crest factor electrosurgical generator. The crest factor is disclosed to be associated with the coagulation effectiveness of the electrosurgical waveform.

U.S. Patent 5,472,443 discloses the variation of tissue impedance with temperature. The impedance of tissue is shown to fall, and then subsequently rise as the temperature is increased. The '443 patent shows a relatively lower temperature region (Region A in Figure 2) where salts, contained within the body fluids, are believed to dissociate, thereby decreasing the electrical impedance. The relatively next higher temperature region (Region B) is where the water in the tissues boils away, causing the impedance to rise. The relatively highest region (Region C) is where the tissue becomes charred, resulting in a slight lowering of impedance.

It would be desirable to have an electrosurgical generator that produced a clinically effective output and, in addition, reduced the amount of heat and thermal spread at the operative site. It would also be desirable to have an electrosurgical generator that produced a better quality seal for vessel sealing and tissue welding operations. It would also be desirable to have an electrosurgical generator that desiccated tissue by applying a minimal amount of electrosurgical energy.

SUMMARY OF THE INVENTION

The present invention relates to an electrosurgical generator having an improved output power controller for increasing the quality and reliability of electrosurgically sealing vessels, sealing
5 ducts, welding and desiccating tissue. In particular, the output power is controlled in a manner that causes impedance of tissue to rise and fall repeatedly until the tissue is completely desiccated. The output power and the tissue impedance are both part of a control system wherein the output power is cycled to thereby cause a cycling of the tissue impedance. A basis for this invention is an experimental observation that the electrical impedance of tissue will usually rise when
10 electrosurgical power is applied, and the electrical impedance of tissue will usually fall when the electrosurgical power is reduced or terminated. Presently available electrosurgical generators will monitor the rising impedance of tissue as power is applied. However, the applicant is the first to design an electrosurgical generator with a power control system that actively cause the impedance of the tissue to rise and fall repeatedly until the tissue is desiccated, and thereby achieve beneficial
15 surgical effects.

The application of electrosurgical power is known to cause the impedance of tissue to fall to a local minimum and then rise monotonically thereafter. If the electrosurgical power is applied for too long, the tissue may char and stick to the electrode. Whereas prior designs terminated output power after the first local minimum in the impedance measurement, the present invention
20 actively causes several local impedance minima to occur. Power can be terminated in the present invention based on an impedance limit, a time limit, or based on the responsiveness of the tissue to changes in output power from the generator.

An advantage of the present invention is that it can coagulate tissue with a reduced level of tissue charring. Another benefit of the present invention is that it has improved tissue sealing
25 characteristics. Yet another benefit of the present invention is that it reduces thermal spread and thereby reduces damage to adjacent tissue. Yet another advantage of the present invention is that it reduces the tendency for eschar buildup on the electrosurgical tool. Yet another advantage of the present invention is that large vessels and ducts can be electrosurgically sealed.

It is thought that impedance of tissue can rise and fall depending on several factors, including output power, output voltage, output current, temperature, and pressure on the tissue exerted by surgical graspers. The present invention addresses changes in impedance of tissue that can be attributed to electrosurgical power application, wherein the power can be adjusted by
5 changing the output voltage or the output current. The present invention causes the tissue impedance to rise and fall repeatedly until the tissue is completely desiccated. The present invention adjusts the output power in a manner that is based on feedback from a tissue impedance measurement.

According to the present invention, the impedance of the tissue rises and falls in response to
10 relatively low frequency cycling of the electrosurgical power. The electrosurgical power is raised and lowered (also referenced herein as "cycled") at a relatively low frequency, and the impedance of the tissue is thereby caused to rise and fall at approximately the same frequency until the tissue becomes desiccated. The manner in which the electrosurgical power is raised and lowered may be accomplished in several ways which incorporate well known principles of control system design.

15 The frequency of power cycling in the present invention is different from the RF modulation frequency of the electrosurgical waveforms, which are typically in the range of one hundred kilohertz to one megahertz. The frequency of power cycling of the present invention is also different from the duty cycle of generators that causes a coagulation effect on tissue, which is typically in the frequency range above one thousand hertz. The frequency range of power cycling
20 in the present invention is typically between one and twenty hertz. Both the RF modulation and the duty cycling of present electrosurgical generators may occur simultaneously with the power cycling of the present invention.

The frequency at which the electrosurgical power is raised and lowered (i.e. cycled or modulated) should not be too high, otherwise the impedance of the tissue will not be able to rise
25 and fall in response with an amplitude that will produce additional benefits. Similarly, the frequency should not be too low, otherwise the beneficial aspects of the invention will not become apparent because the tissue will desiccate without any appreciable modulation. The range of effective frequencies of the present invention has been called "thermal bandwidth."

The behavior of the tissue impedance is possibly related to the thermal time constant of the tissue. There are additional factors that affect the tissue impedance, including the water content in the tissue and steam. After the tissue is desiccated, which is indicated by a high measured impedance, further application of electrosurgical power will cause undesirable charring. Thus, it is preferred to have impedance monitoring to determine the appropriate time for terminating the electrosurgical power. Impedance monitoring is also preferred so that the modulation frequency of the electrosurgical power can be automatically adjusted and kept within the thermal bandwidth.

It is theorized by the inventor that thermal spread during electrosurgical desiccation is created in at least three ways. The first is through direct thermal conduction away from the weld site. The second is from hot steam exiting the weld site. This mechanism is perhaps far more significant than the first, because of the steam's high mobility. The third mechanism is the lateral spread of current away from the weld site. It is theorized that the third mechanism is due to steam creating a high impedance pathway between the jaws, which forces a larger portion of the current to flow laterally. The present invention controls the output power in a manner that reduces thermal spread.

The present invention is relevant to all electrosurgical generators. It has been found to be particularly relevant to bipolar electrosurgical applications, as well as to electrosurgical tissue welding and vessel sealing. Skilled practitioners will recognize the value of the invention wherever tissue desiccation is accomplished by electrosurgical methods.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram representation of an adaptive oscillatory power curve according to the present invention.

Figure 2(a) is a sample of experimental data for a standard vessel sealing operation, showing output power as function of time.

Figure 2(b) is a sample of experimental data for a standard vessel sealing operation, showing load impedance as a function of time.

Figure 2(c) is a sample of experimental data for a standard vessel sealing operation, showing output current as a function of time.

Figure 2(d) is a sample of experimental data for a standard vessel sealing operation, showing output voltage as a function of time.

5 Figure 3(a) is a sample of experimental data for an adaptive power control generator, showing output power as function of time.

Figure 3(b) is a sample of experimental data for an adaptive power control generator, showing load impedance as a function of time.

10 Figure 3(c) is a sample of experimental data for an adaptive power control generator, showing output current as a function of time.

Figure 3(d) is a sample of experimental data for an adaptive power control generator, showing output voltage as a function of time.

Figure 4(a) is a representation of a power curve for a standard electrosurgical generator.

Figure 4(b) is a representation of an adaptive oscillatory power curve.

15

DETAILED DESCRIPTION OF THE INVENTION

20 The present invention discloses an adaptive, oscillatory power curve which is able to reduce thermal spread in each of these areas by applying power in a cyclical fashion, rather than continuously. During the periods of reduced power application, thermal energy is allowed to dissipate which reduces direct thermal conduction. Also, the steam exits the weld site in smaller bursts, which produces less thermal damage than one large burst. Finally, the impedance between the jaws of the electrosurgical instrument is kept low, which allows current to flow more directly between the jaws.

25 Charring is also reduced. High voltages contribute to tissue charring, which is why it is preferable to limit the output voltage of the electrosurgical generator to 120 volts, and to periodically reduce it to a lower value during power cycling. A relatively low voltage is also important because it prevents electrical sparks, or arcs, from passing through the tissue and burning small holes in the newly sealed, or welded, tissue.

The transparency, or clarity, at the weld site has been identified as an indicator of successful seal completion. It also gives the surgeon visual feedback as to whether the seal is a success. Preliminary findings indicate that this method may also increase weld site transparency. The reason for this is unknown, but it seems reasonable that reduced charring will allow the weld site to remain more transparent.

Referring to Figure 1, a block diagram of an adaptive oscillatory power control system 10 is shown. The line designated by the letter A represents the command input signal to the control system 10. The command input signal A is preferably a periodic function, and in certain embodiments the period may vary depending on the dynamics of the tissue. The signal A is representative of the desired tissue impedance. A measurement of tissue impedance is represented by line B. A summing block 11 compares the command input signal A with the measured tissue impedance B to produce a difference signal C. The summing block 11 may be comprised of an electrical comparator circuit as is commonly known to control systems engineers.

The difference signal C may be input to a controller 12 that generates a control signal D. The control signal D adjusts or terminates the output power of the electrosurgical generator by changing the state of the R.F. Output Stage 13. The controller 12 may be comprised of an algorithm in a microprocessor that determines the conditions for power termination based on the amplitude of the control signal. Alternatively and equivalently, the controller 12 may be connected directly to the measured tissue impedance B to terminate power based on the amplitude of the measured tissue impedance B. The controller 12 may be comprised of any combination of proportional, integral, and derivative control laws that are known to control system engineers. Other types of control laws, such as "bang-bang" control laws, are effective equivalents.

In one embodiment, the command input signal A has a cyclic pattern, for example a sine wave or a square wave. The cyclic nature of the command input signal A causes the control system 10 to regulate the output power in a cyclic manner to achieve beneficial surgical effects. The controller 12 monitors the difference signal C to determine the response of the output power E. In one embodiment, when the difference signal C is large, and the impedance measurement B is above a threshold, then the controller 12 terminates the output power E.

The control signal D is preferably connected to an R.F. Output Stage 13. The control signal D preferably changes a driving voltage in the R.F. output stage to thereby change the RMS output power from the electrosurgical generator, shown as line E in Figure 1. Alternatively and equivalently, the control signal D may change the duty cycle of the R.F. Output Stage 13 thereby effectively changing the RMS output power. Other means of changing RMS output power from an R.F. Output Stage, such as changing current, are known to electrical engineers.

The generator R.F. Output Stage 13 causes the electrosurgical generator to output a power level E to the tissue 14 of the patient. The tissue 14 becomes desiccated, thereby changing the electrical impedance, shown by F in Figure 1. The electrical impedance F of the tissue is measured by an impedance measurement circuit 15 and reported as the measured tissue impedance B. The impedance measurement circuit 15 may be any form of electrical circuit that measures, or estimates, electrical impedance. The measured tissue impedance B is preferably an electrical signal that is proportional to the actual tissue impedance F.

Electrical engineers will recognize that output power from an electrosurgical generator can be adjusted in several ways. For example, the amplitude of the output power can be adjusted. In another example, the output power can be adjusted by changing the duty cycle or the crest factor. The change or adjustment in output power, as used herein, is meant to refer any change or adjustment in the root mean square (RMS) value of the output power of the electrosurgical generator.

In operation, the control system 10 is designed to cycle the tissue impedance F for preferably several cycles in order to achieve beneficial effects. Thus, the command input signal A is a cyclically varying signal, such as a sine wave. An example of cyclical impedance behavior of tissue is shown in Figure 3(b). The generator output power that caused the cyclical impedance behavior is shown in Figure 3(a). The cyclical behavior of the present invention can be contrasted with a standard electrosurgical generator wherein the output power is shown in Figure 2(a) and the tissue impedance is shown in 2(b).

The present invention discloses an adaptive, oscillatory power curve which is able to reduce thermal spread in each of these areas by applying power in a cyclical fashion, rather than continuously. During the periods of reduced power application, thermal energy is

allowed to dissipate which reduces direct thermal conduction. Also, the steam exits the weld site in smaller bursts, which produces less thermal damage than one large burst. Finally, the impedance between the jaws of the electrosurgical instrument is kept low, which allows current to flow more directly between the jaws.

5 Charring is thought to be reduced by the present invention. High voltages contribute to tissue charring, which is why it is preferable to limit the output voltage of the electrosurgical generator to 120 volts, and to periodically reduce it to a lower value during power cycling. A relatively low voltage is also important because it prevents electrical sparks, or arcs, from passing through the tissue and burning small holes in the newly sealed, or
10 welded, tissue.

The transparency, or clarity, at the weld site has been identified as an indicator of successful seal completion. It also gives the surgeon visual feedback as to whether the seal is a success. Preliminary findings indicate that this method may also increase weld site transparency. The reason for this is unknown, but it seems reasonable that reduced charring
15 will allow the weld site to remain more transparent.

A plot of output power vs. load impedance is called a "power curve." A representation of a standard power curve is shown in Figure 4(a). At low impedance, the output is typically current limited, and this is shown as the "constant current" line segment on Figure 4(a). At midranges of impedance, the electrosurgical generator has a power control
20 system that maintains the output power at a constant level by adjusting the output voltage, as shown by the "constant power" line segment on Figure 4(a). Eventually, the load impedance becomes large, and the output power cannot be maintained without applying unacceptably high output voltages. Thus, a voltage limit is reached, and the output power drops off because the output current is falling and the output voltage is at a limit. The drop in output power is
25 shown as the "constant voltage" line segment in Figure 4(a).

The present invention is related to an electrosurgical generator having an adaptive oscillatory power curve as shown in Figure 4(b). The adaptive oscillatory power curve is produced by a power control system in the electrosurgical generator. The design details of the

control system can be implemented in several ways which are well known to control system engineers.

The first part of the adaptive oscillatory power curve, shown at the line segment I in Figure 4(b), is similar to the standard power curve, wherein the generator applies high current into a low impedance load until a maximum power limit, shown as A, is reached. In the next “leg” of the power curve, shown by line segment B, output current begins to fall, and output voltage begins to rise as the generator adjusts the output voltage to maintain constant output power at the level marked by A. The generator then begins looking for signs to indicate the onset of boiling in the tissue. Such signs include a very rapid rise in impedance, or a high value of voltage, such as 120 volts. The local maximum of the impedance curve is shown by letter K in Figure 4(b). The dotted line, marked C and labeled $V=120\text{ V}$, shows the possible output power if the generator were to maintain a voltage limit of 120 volts, which is a preferred voltage limit. Rather than follow the $V=120\text{ V}$ line, a controller in the generator drops the output power. This can be accomplished, in one embodiment, by dropping the output voltage limit to between zero and 70 volts, and preferably 50 volts, as shown in line segment D. In another embodiment of the control system, the output power can be reduced by other combinations of output current reduction and/or output voltage reduction.

As a consequence of the lower voltage limit, the output power drops to the level indicated by H in Figure 4(b). In certain embodiments, H may be zero watts. At this lower output power, desiccation stops and the tissue impedance starts to fall. A preferred lower voltage limit of 50 volts may be used as shown by dotted line E and marked “ $V=50\text{ volts}$ ”. Once the impedance has reached a local minimum, shown by J, or after a set period of time, the power control system raises the output power back to level A, which corresponds to an output voltage limit of 120 volts in the preferred embodiment. Thus, the output power rises back to level A, and the impedance rises again, until the onset of boiling or an impedance threshold is reached. The cyclical portion of the power curve incorporating line segments B, D, and E is an important part of this invention and will continue until the tissue is desiccated. When the tissue is desiccated, the power will terminate as shown when impedance reaches point L. In certain embodiments, point L will be substantially the same as point K.

The behavior shown in Figure 4(b) can be observed in Figures 3(a), 3(b), 3(c) and 3(d). Power oscillations between 120 watts and 20 watts in Figure 3(a) correspond to cyclical movement between power level A and power level H in Figure 4(b). Impedance oscillations in Figure 3(b) correspond to cyclical movement between impedance level K and impedance level J in Figure 4(b). It will be understood by control systems engineers that Figure 4(b) is highly idealized, and the cyclical behavior may not always reach exactly the same local maxima and minima. This can be observed in Figure 3(a), where the local maxima of the power curve may not always reach 120 volts.

It is theorized by the inventor that the following phenomena occur. The initial high output power initiates boiling in the tissues. The subsequent low output power is insufficient to maintain boiling, and hence boiling in the tissue stops. After boiling stops, if the tissue is not completely desiccated then the impedance will fall to a lower value. Next, the low impedance allows output power to increase, which re-heats the tissue to the point of boiling. The voltage is also pulled higher during the process, and remains so until the power curve can sense the onset of boiling, and lower the voltage, preferably back to 50 volts. The process continues until the tissue is fully desiccated. An oscillation is one cycle of high output power followed by low output power.

Figures 2(a) through 2(d) show experimental results on tissue samples using a standard power curve. Figures 3(a) through 3(d) show experimental results using an adaptive oscillatory power curve. The general nature of the invention can be seen by comparing Figure 2(a) with Figure 3(a). Figure 2(a) shows a 100 watt electrosurgical output that is applied continuously to tissue. As the tissue desiccates, the impedance of the tissue rises and the output power in Figure 2(a) is seen to fall off below 20 watts. In contrast, Figure 3(a) shows an oscillating output power that varies from approximately 100 watts to approximately 20 watts. The effects on tissue impedance can be seen by comparing Figure 2(b) with Figure 3(b). The tissue impedance resulting from the standard power curve is shown to continuously increase in Figure 2(b), perhaps after an initial drop. The tissue impedance resulting from the adaptive oscillatory power curve is shown to oscillate in Figure 3(b) and thus has several local minima.

Output voltage and output current show a cyclic behavior in the adaptive oscillatory power curve. The cyclic behavior is absent in the standard power curve. Figures 2(c) and 3(c) can be compared to show the difference in output current between the standard power curve and the adaptive oscillatory power curve. In each case the maximum output current rises above 2 amps RMS. Figures 2(d) and 3(d) can be compared to show the difference in output voltage between the standard power curve and the adaptive oscillatory power curve. A voltage limit, preferably in each case 120 volts, prevents arcing that might leave pinholes in the tissue seal.

In one embodiment of the adaptive oscillatory power curve, the generator temporarily lowers the output voltage limit to 50 volts whenever the output voltage reaches 120 volts. This causes a reduction in output power, and if the tissue is not completely desiccated, a corresponding significant reduction in tissue impedance. After the reduction in tissue impedance, the output voltage limit is reset to 120 volts, allowing a rise in output power. This reduction and subsequent rise in output power constitutes a cycle.

Designers of electrosurgical generators have found that impedance is a good indicator of the desiccation state of the tissue. However, skilled artisans will recognize that it may not be necessary to compute an exact value for impedance. An electrical measurement that is proportional to the tissue impedance can be used as a functional equivalent. In one embodiment, the control system can properly create the adaptive oscillatory power curve based on measurements of time, and output voltage.

Table 1 shows a comparison between two sets of tests which compare a standard power curve with an adaptive oscillatory power curve. Test 1 indicates use of the standard power curve, while Test 2 indicates the use of the adaptive oscillatory power curve. Size indicates the vessel diameter in millimeters, burst pressures are measured in p.s.i., sticking, charring, and clarity are subjective measures ranked from 0 to 3, (where 0 represents a low value for sticking and charring, and 0 represents a poor value for clarity), and ts indicates thermal spread, measured in millimeters.

Table 1. Comparison of Standard Power Curve with Adaptive Power Curve

Test	#samples	size	bp	stick	charring	clarity	ts
1 (mean)	19	2.57	17.26	.63	1.11	1.89	2.11

1 (SD)		1.35	1.04	.76	.81	1.29	.74
1 (min)		1	12.96				
1 (max)		6	17.50				
2 (mean)	20	2.55	17.39	.80	.60	1.95	1.65
2 (SD)		1.36	.44	1.06	.60	1.36	.81
2 (min)		1	15.52				
2 (max)		5	17.50				

Table 1 illustrates that the adaptive oscillatory power curve (Test 2) has several advantages over the standard power curve (Test 1). Most notable is the lower amount of thermal spread: a mean value of 2.11mm for the standard power curve, and 1.65mm for the adaptive oscillatory power curve. The subjective measures for sticking, charring, and clarity of the weld show that the adaptive oscillatory power curve offer improvements over the standard power curve.

In general, the invention is an electrosurgical generator for treating tissue, wherein the electrosurgical generator comprises a circuit for generating a measurement of the load impedance, and an output power controller having means for inducing multiple oscillations of the load impedance in response to the measurement. The load impedance refers to the impedance of the tissue being treated by the electrosurgical generator. The circuit for generating a measurement of the load impedance can be analog or digital, and typically requires an output voltage sensor and an output current sensor. The output voltage is divided by the output current to compute a measurement of load impedance.

The means for inducing multiple oscillations of the load impedance preferably comprises a control system which can selectively control the output voltage to cause appropriate oscillations of the output power. In many electrosurgical generators, an output power control circuit has an adjustable voltage supply connected to the primary side of an isolation transformer. The secondary winding of the transformer is connected to an output resonant circuit. The voltage supply has an adjuster for changing the voltage to the transformer, and thereby changing the output voltage of the electrosurgical generator. A digital signal may be used to control the voltage supply.

The means for inducing multiple oscillations preferably comprise a feedback control system, where the feedback is a measurement of the load impedance. The control system

preferably includes an algorithm in a microprocessor. The algorithm in the microprocessor can monitor the load impedance and determine how the load impedance is responding to a change in the output power.

In the preferred embodiment, the control system sets an output voltage limit of 120
5 volts RMS, and then controls the output power to a user desired setting, for example 100
watts. When the impedance is relatively low, a high current will combine with an output
voltage of less than 120 volts to yield the desired power of 100 watts. As the impedance rises,
the output current will fall, and the output voltage will be increased by the circuit to maintain
the desired output power. When the voltage limit of 120 volts is reached, the control system
10 will automatically lower the output voltage to a low value, preferably 50 volts. This
effectively lowers the output power. If the tissue is not completely desiccated, the lower
output power will cause the impedance to drop significantly. Once a local impedance
minimum is detected, or after a set period of time, the output voltage limit is reset to 120 volts
by the control system, and the cycle repeats. It has been found through experimentation that
15 the oscillations of the load impedance will occur in the frequency range of one to twenty hertz,
and this range has been referred to herein as the thermal bandwidth. In one embodiment, the
control system terminates the output power after a set period of time which was three
seconds. Alternatively, the control system can terminate power when the impedance reaches a
threshold of 2000 ohms. Another alternative is to terminate output power when the
20 measurement of impedance indicates that the impedance does not substantially fall in response
to a drop in the output power.

The present invention is applicable to any form of electrosurgical coagulation. The benefits
of the present invention, including reduced thermal spread, less eschar buildup, and improved
desiccation, can be applied to both monopolar and bipolar electrosurgical generator outputs. While
25 a particular preferred embodiment has been illustrated and described, the scope of protection
sought is in the claims that follow.

WHAT IS CLAIMED:

1. An electrosurgical generator for applying energy to tissue to desiccate tissue, the controller comprising:
 - a controller for cycling the output power to cause a cycling of the tissue impedance; and
 - a tissue impedance measurement circuit for measuring impedance of the tissue;wherein the controller terminates output power when the measured tissue impedance exceeds a predetermined value, the predetermined value corresponding to a desiccated condition of tissue.
2. The generator of claim 1, wherein the controller changes the output voltage to cycle the output power.
3. The generator of claim 1, wherein the controller changes the output current to cycle the output power.
4. The generator of claim 1, wherein the output voltage is cycled by lowering the output voltage once it reaches a predetermined maximum and raising the output voltage if the reduction in measured tissue impedance does not indicate desiccation of the tissue.
5. The generator of claim 1, wherein the output power is cycled at a relatively low frequency.
6. The generator of claim 5, wherein the frequency is between 1 and 20 Hz.
7. The generator of claim 6, wherein the output voltage does not exceed 120 volts.

8. The generator of claim 1, further comprising a comparator wherein the measured tissue impedance value is compared to a first signal representative of a desired tissue impedance value by the comparator and a difference signal is produced.

9. The generator of claim 8, wherein the difference signal is input to the controller which generates a signal to adjust the power.

10. The generator of claim 8, wherein the first signal has a cyclic pattern.

11. The generator of claim 10, wherein the first signal is a sine wave.

12. An electrosurgical generator for treating tissue by applying electrosurgical energy comprising:

means for minimizing the burning of tissue, the minimizing means comprising a controller for repeatedly increasing and decreasing output power to the tissue to be treated, the controller adjusting the output power in response to the degree of desiccation of the tissue.

13. The generator of claim 12, wherein the output power is terminated upon detection of desiccated tissue.

14. The generator of claim 13, wherein the degree of desiccation of the tissue is determined by the measured impedance of the tissue.

15. The generator of claim 14, wherein the output power is adjusted by adjusting the output voltage within a predetermined voltage range.

16. The generator of claim 12, wherein the output power is repeatedly increased and decreased at a frequency between 1 and 20 Hz.

17. A method for applying energy to tissue to treat tissue, the method including supplying a generator having a power control system to produce an adaptive oscillatory power curve to minimize the heating effect on tissue, the method comprising:

- a) applying a high current into a low impedance load until a maximum power is reached;
- b) adjusting the output voltage to maintain constant output power as impedance increases as tissue begins to desiccate;
- c) dropping the output power in response to a rapid rise in tissue impedance indicating the boiling of tissue;
- d) allowing the tissue impedance to fall to a predetermined minimum value and then raising the output power to cause an increase in tissue impedance;
- e) repeating steps b and c until impedance reaches a maximum value.

18. A method for applying energy to tissue to treat tissue, the method including supplying a generator having a power control system to produce an adaptive oscillatory power curve to minimize the heating effect on tissue, the method comprising:

- a) applying a high current into a low impedance load until a maximum power is reached;
- b) adjusting the output voltage to maintain constant output power as impedance increases as tissue begins to desiccate;
- c) dropping the output power if the output voltage exceeds a maximum value;
- d) raising the output power after a predetermined period of time to cause an increase in tissue impedance; and
- e) repeating steps b and c until impedance reaches a maximum value.

ELECTROSURGICAL GENERATOR WITH ADAPTIVE POWER CONTROL

An electrosurgical generator has an output power control system that causes the impedance of tissue to rise and fall in a cyclic pattern until the tissue is desiccated. The advantage of the power control system is that thermal spread and charring are reduced. In addition, the power control system offers improved performance for electrosurgical vessel sealing and tissue welding. The output power is applied cyclically by a control system with tissue impedance feedback. The impedance of the tissue follows the cyclic pattern of the output power several times, depending on the state of the tissue, until the tissue becomes fully desiccated. High power is applied to cause the tissue to reach a high impedance, and then the power is reduced to allow the impedance to fall. Thermal energy is allowed to dissipate during the low power cycle. The control system is adaptive to tissue in the sense that output power is modulated in response to the impedance of the tissue.

15

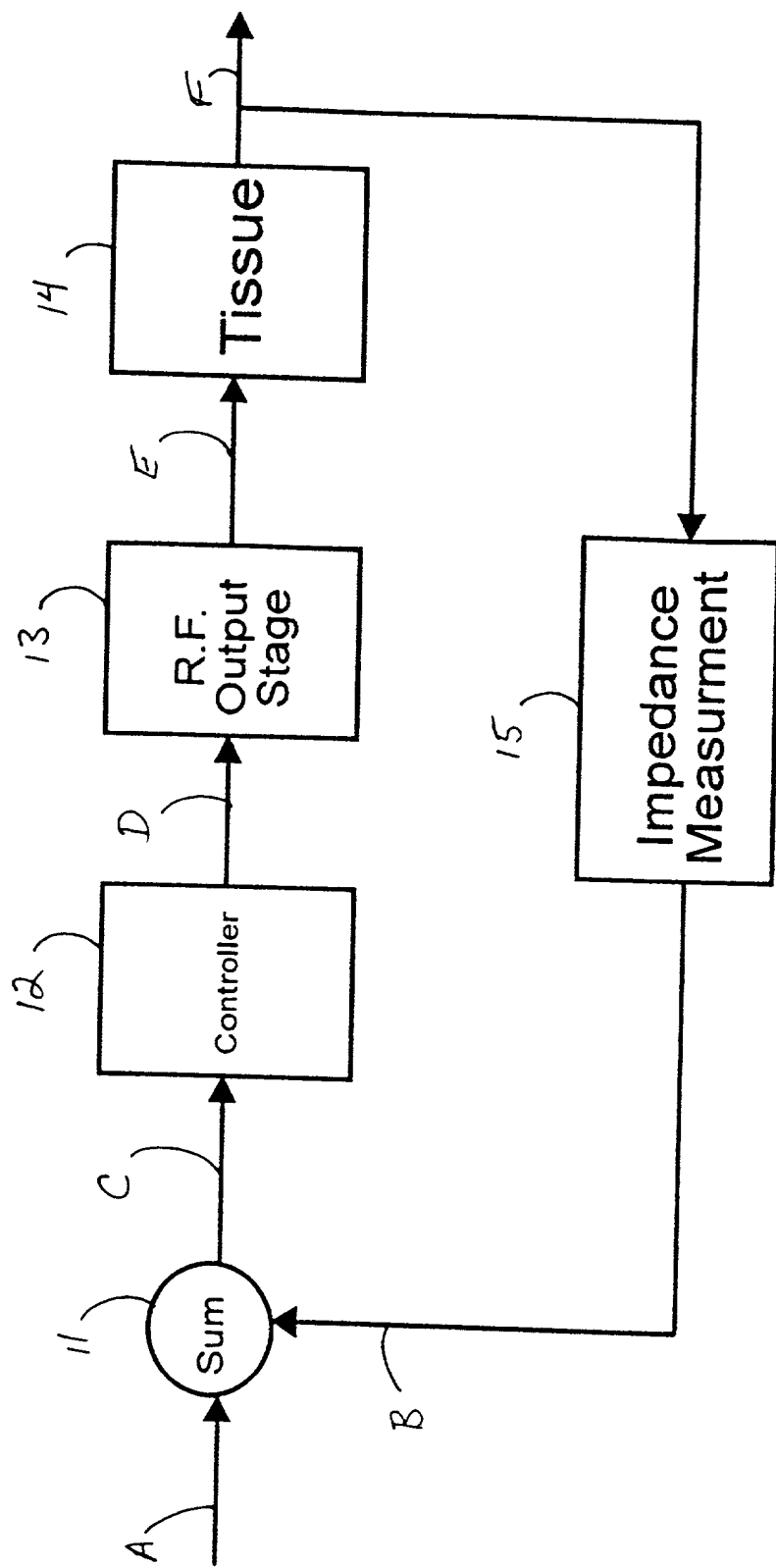


FIG. 1

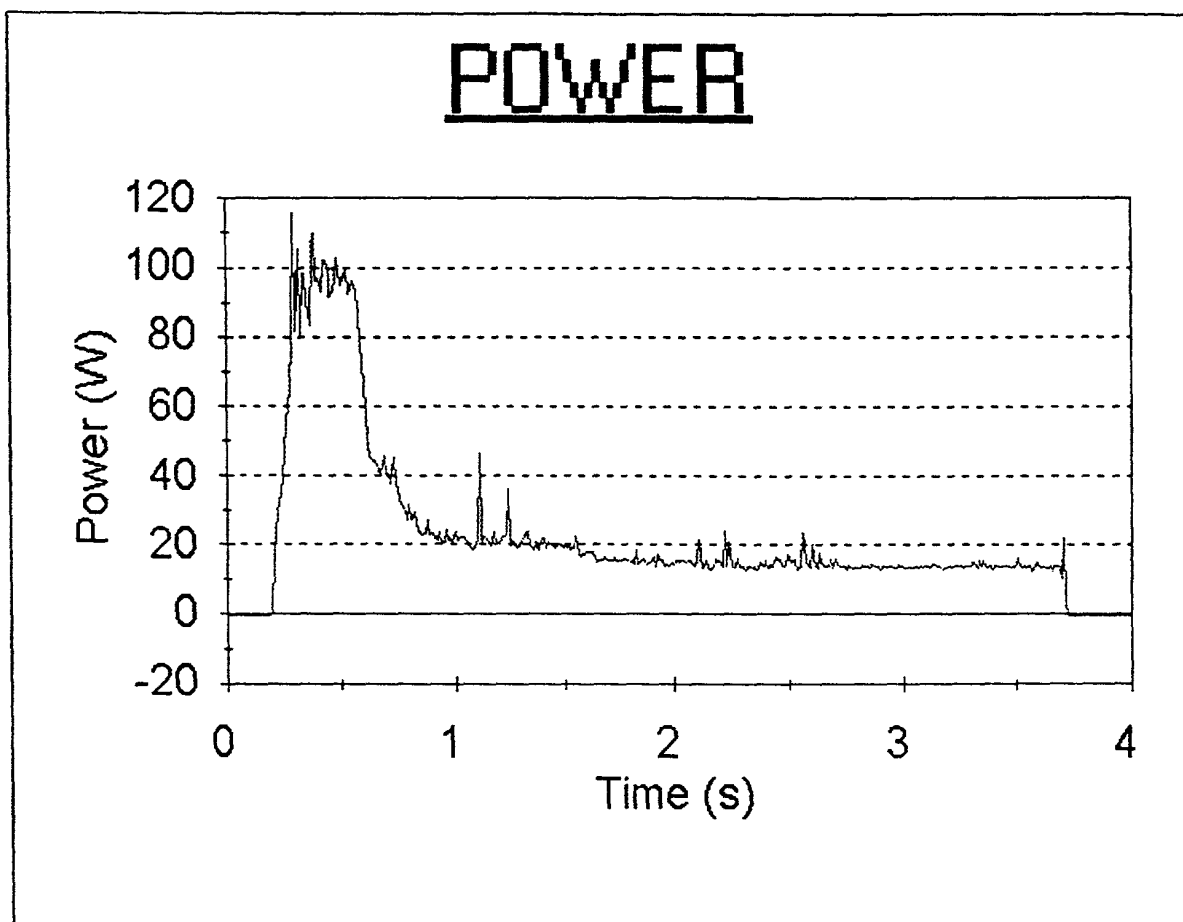


FIGURE 2(a)

IMPEDANCE

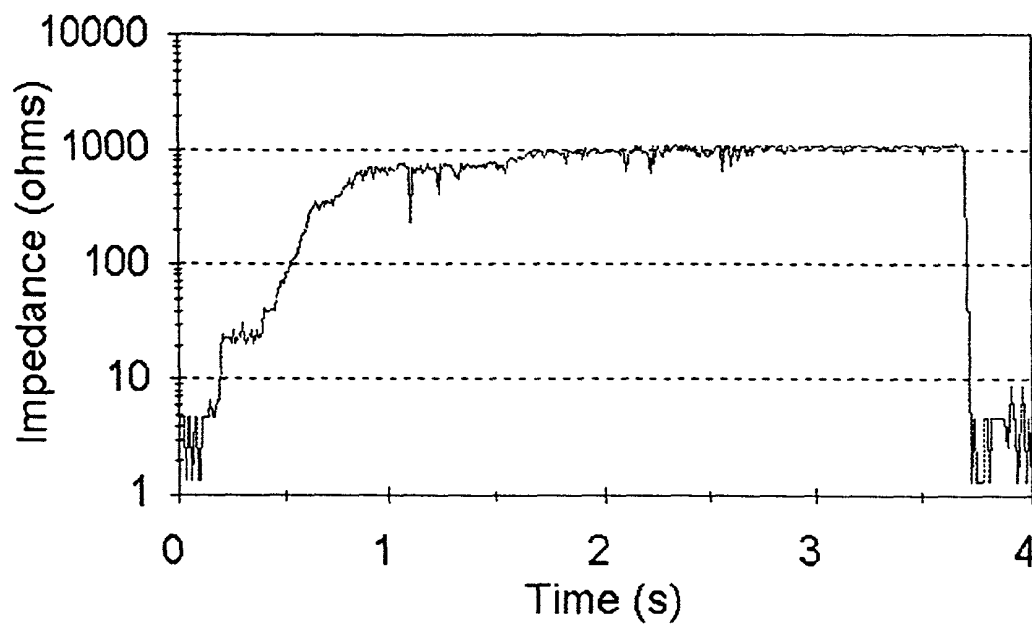


FIGURE 2(b)

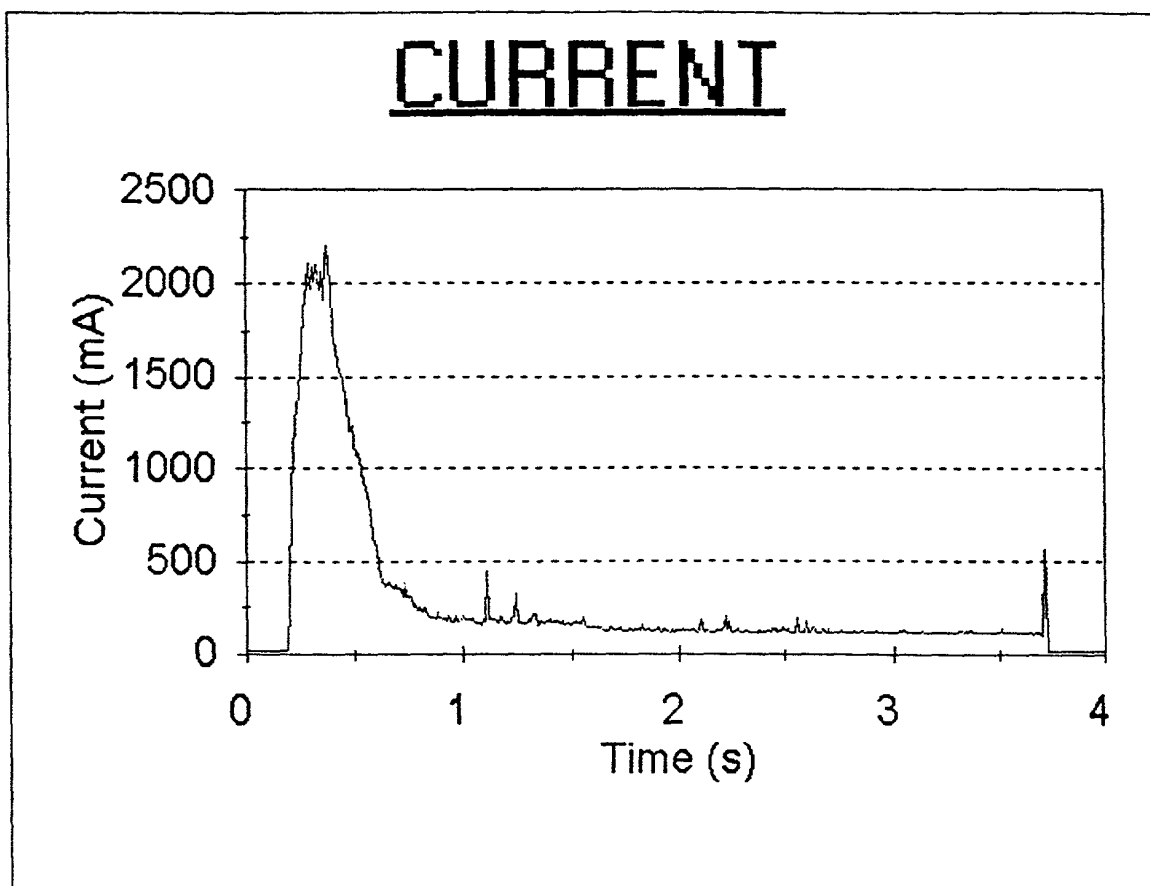


FIGURE 2(c)

VOLTAGE

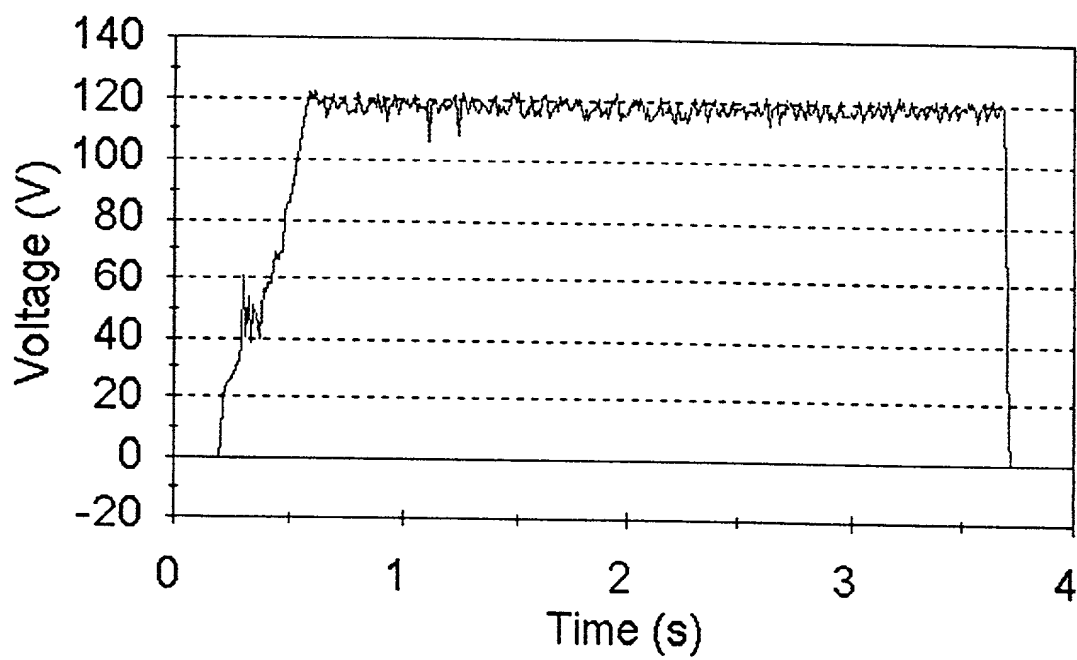


FIGURE 2(d)

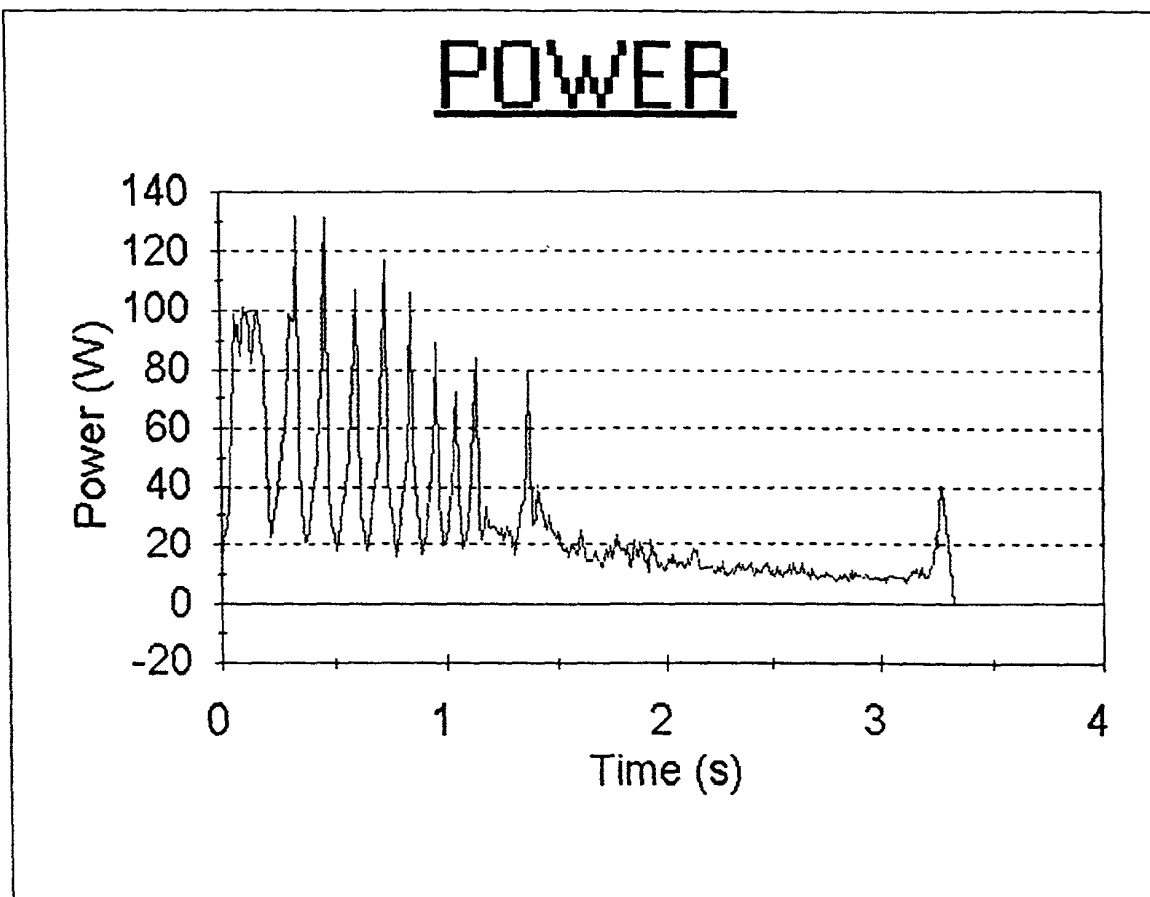


FIGURE 3(a)

IMPEDANCE

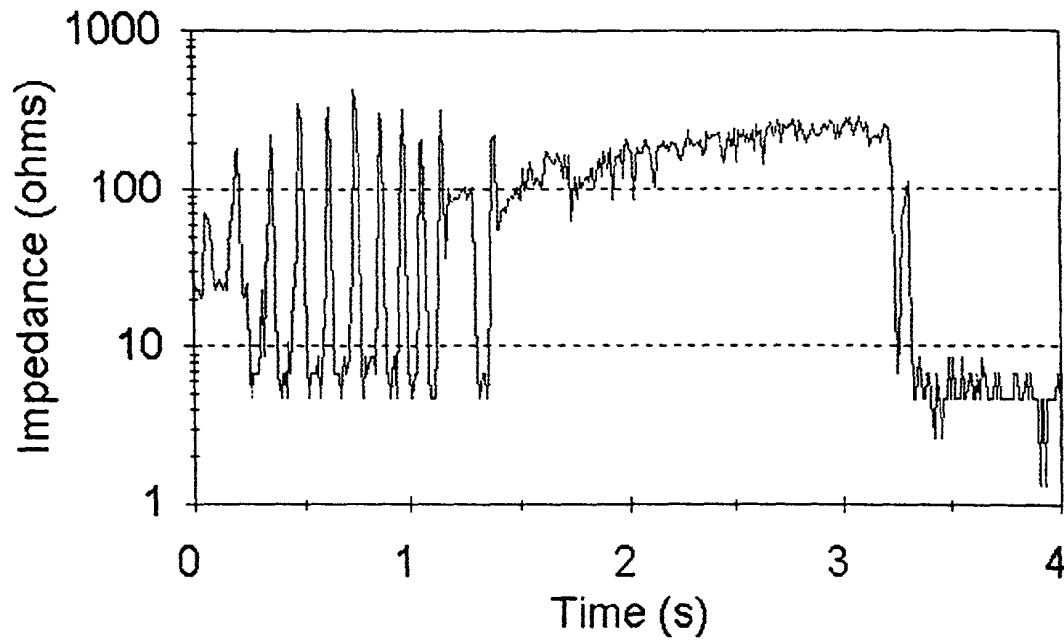


FIGURE 3(b)

CURRENT

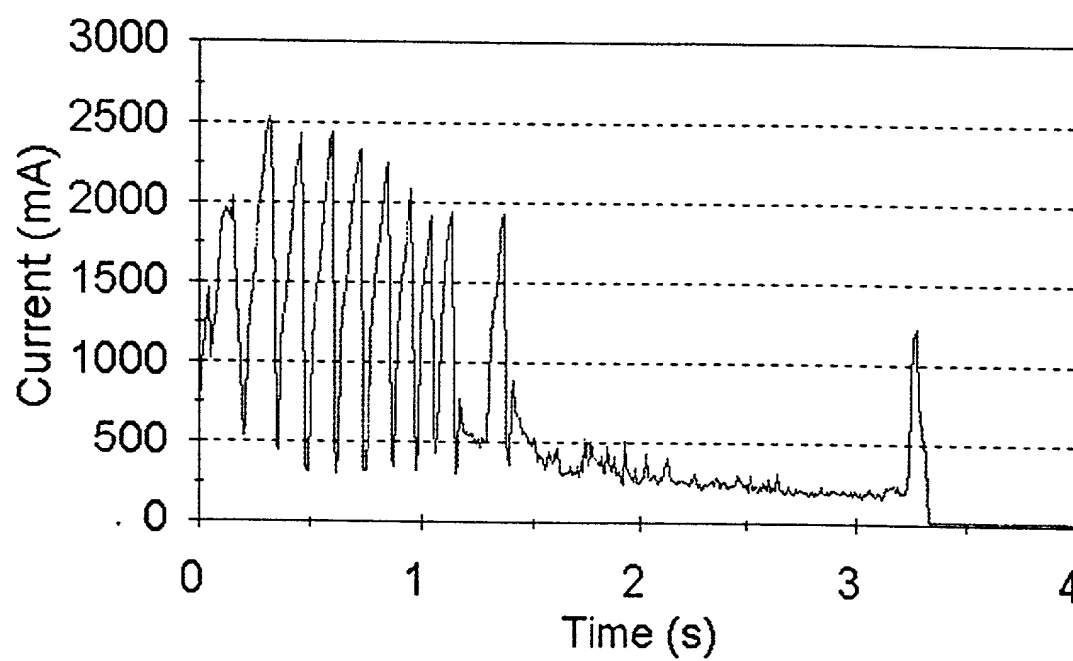


FIGURE 3(c)

VOLTAGE

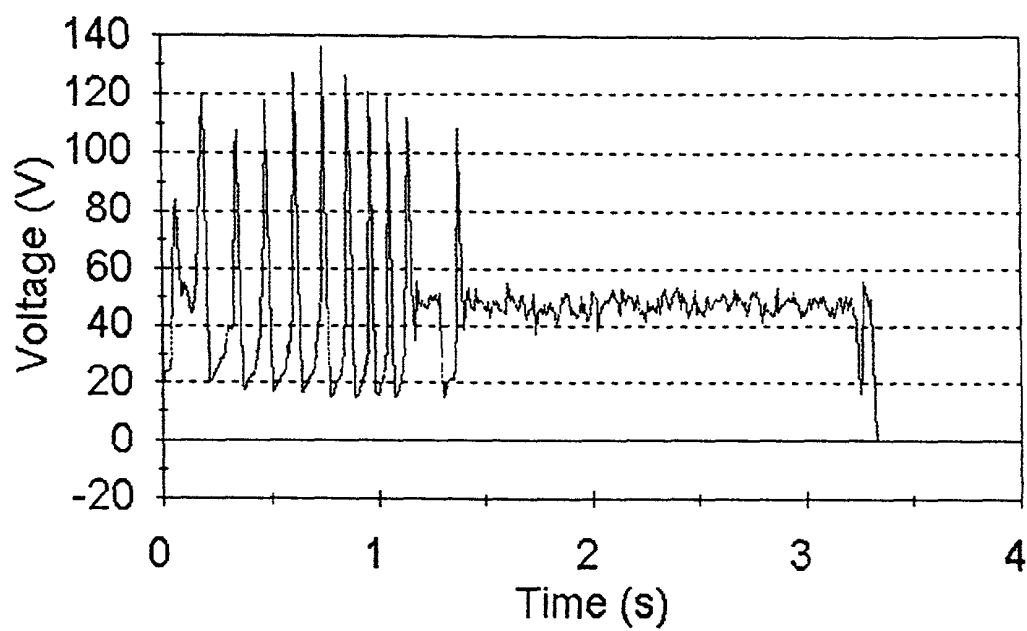


FIGURE 3(d)

Power

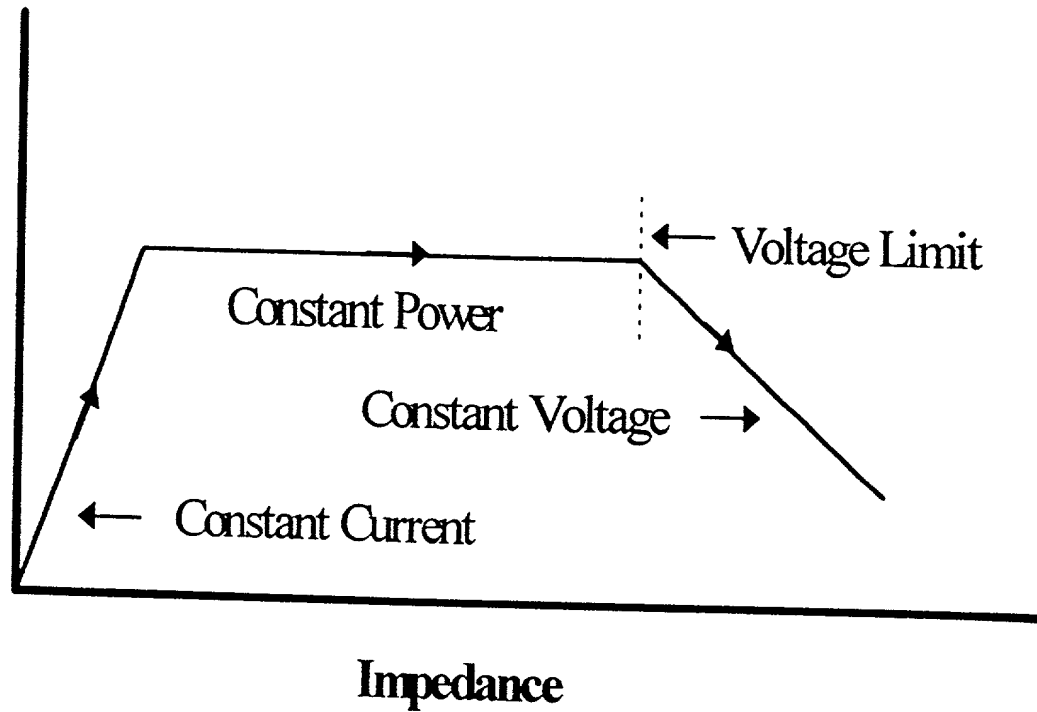


FIGURE 4(a)

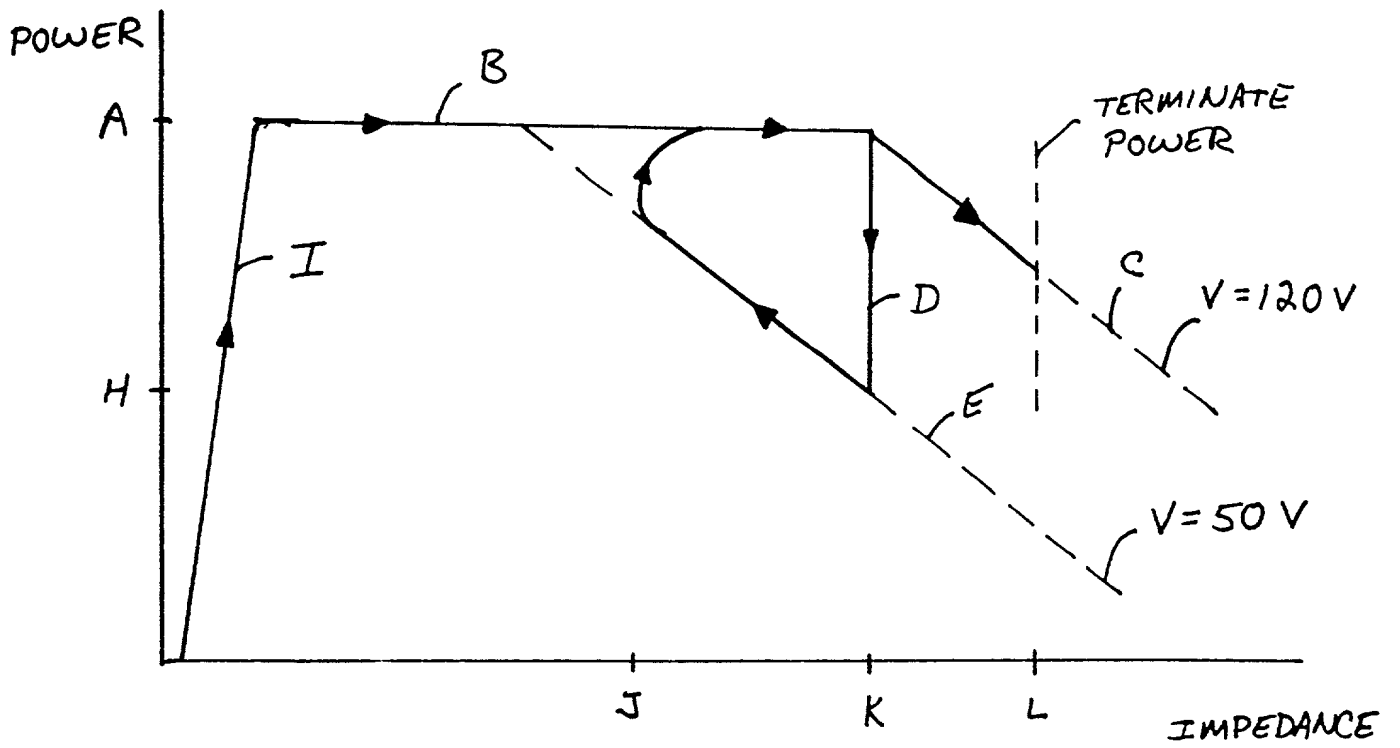


FIGURE 4(b)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Electrosurgical Generator with Adaptive Power Control

the specification of which (check only one item below):

X is attached hereto

_____ was filed as United States application

Serial No. _____

on

and was amended

on _____ (if applicable).

 was filed as PCT international application

Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
--------	---	---	---	---	---	---	---	---	---	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	-----

on _____

and was amended under PCT Article 19

on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

[illegible]

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications) Page 2 of 4Docket Number
PC9743ALP

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U. S. APPLICATIONS			STATUS (CHECK ONE)		
U. S. APPLICATION NO.	U. S. FILING DATE		PATENTED	PENDING	ABANDONED
PCT APPLICATIONS DESIGNATING THE U.S.			PATENTED	PENDING	ABANDONED
PCT APPLICATION NUMBER	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

SEE ATTACHED LIST

Send Correspondence to:

Dr. Peter C. Richardson,
PFIZER INC, 235 East 42nd Street,
New York, NY 10017-5755, U.S.A.

Direct Telephone Calls To:

Aaron Passman (303) 581-6614

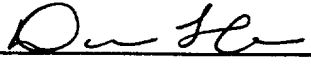
201	FULL NAME OF INVENTOR	FAMILY NAME GINES	FIRST GIVEN NAME DAVID	SECOND GIVEN NAME LEE
	RESIDENCE & CITIZENSHIP	CITY BOULDER	STATE OR FOREIGN COUNTRY COLORADO	COUNTRY OF CITIZENSHIP UNITED STATES OF AMERICA
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 1300 30TH STREET D10-16	CITY BOULDER	STATE/ZIP CODE/COUNTRY COLORADO 80303 U.S.A.
202	FULL NAME OF INVENTOR			
	RESIDENCE & CITIZENSHIP			
	POST OFFICE ADDRESS			
203	FULL NAME OF INVENTOR			
	RESIDENCE & CITIZENSHIP			
	POST OFFICE ADDRESS			
204	FULL NAME OF INVENTOR			
	RESIDENCE & CITIZENSHIP			
	POST OFFICE ADDRESS			

COMBINED DECL. & P. OF A.

205	FULL NAME OF INVENTOR			
	RESIDENCE & CITIZENSHIP			
	POST OFFICE ADDRESS			
206	FULL NAME OF INVENTOR			
	RESIDENCE & CITIZENSHIP			
	POST OFFICE ADDRESS			
207	FULL NAME OF INVENTOR			
	RESIDENCE & CITIZENSHIP			
	POST OFFICE ADDRESS			
208	FULL NAME OF INVENTOR			
	RESIDENCE & CITIZENSHIP			
	POST OFFICE ADDRESS			

COMBINED DECL. & P. OF A.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR (201)		
		
DATE		
March 25, 1997		

POWER OF ATTORNEY (CONTINUED)

PETER C. RICHARDSON, Reg. No. 27,526; MICHAEL J. PANTULIANO, Reg. No. 18,971; ALLEN J. SPIEGEL, Reg. No. 25,749; AARON PASSMAN, Reg. No. 26,783; GEZINA HOLTRUST, Reg. No. 28,222; J. TREVOR LUMB, Reg. No. 28,567; LAWRENCE C. AKERS, Reg. No. 28,587; RAYMOND W. AUGUSTIN, Reg. No. 28,588; SEYMOUR G. BEKELNITZKY, Reg. No. 28,589; PAUL H. GINSBURG, Reg. No. 28,718; MARK DRYER, Reg. No. 28,775; ELIZABETH O. SLADE, Reg. No. 29,011; JOHN L. LAPIERRE, Reg. No. 29,185; ERIC M. LEE, Reg. No. 30,471; JAMES T. JONES, Reg. No. 30,561; GREGG C. BENSON, Reg. No. 30,997; A. DEAN OLSON, Reg. No. 31,185; ROBERT F. SHEYKA, Reg. No. 31,304; HOWARD R. JAEGER, Reg. No. 31,376; GROVER F. FULLER, JR., Reg. No. 31,760; MERVIN E. BROKKE, Reg. No. 32,723; KAREN DEBENEDICTIS, Reg. No. 32,977; VALERIE M. FEDOWICH, Reg. No. 33,688; PHILIP C. STRASSBURGER, Reg. No. 34,258; BRYAN C. ZIELINSKI, Reg. No. 34,462; ROBERT T. RONA, Reg. No. 36,257; and GARTH BUTTERFIELD, Reg. No. 36,997.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): David L. Gines

Serial No.: 08/838,548

Filed: 04/09/97

For: Electrosurgical Generator With Adaptive Power Control

Revocation and Substitute Power of Attorney

Asst. Commissioner for Patents
Washington, D.C. 20231

Sir:

Valleylab Inc, as assignee of the entire interest in the above patent application, hereby revokes all Powers of Attorney previously given in this case and hereby appoints, with full power of substitution and revocation, to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith,

JOHN C. ANDRES, Reg. No. 30,931; NEIL D. GERSHON, Reg. No. 32,225; BASAM E. NABULSI, Reg. No. 31,645; MARK FARBER, Reg. No. 34,159; NEIL Y. GILBERT, Reg. No. 35,156; and CAROLYN H. BLANKENSHIP, Reg. No. 35,449; each of them of United States Surgical Corporation, 150 Glover Avenue, Norwalk, Connecticut 06856.

PETER G. DILWORTH, Reg. No. 26,450; ROCCO S. BARRESE, Reg. No. 25,253; DAVID M. CARTER, Reg. No. 30,949; PAUL J. FARRELL, Reg. No. 33,494; PETER DELUCA, Reg. No. 32,978; ADRIAN T. CALDERONE, Reg. No. 31,746; GEORGE M. KAPLAN, Reg. No. 28,375; JEFFEREY S. STEEN, Reg. No. 32,063; JOSEPH W. SCHMIDT, Reg. No. 36,920; RAYMOND E. FARRELL, Reg. No. 34,816; RUSSELL R. KASSNER, Reg. No. 36,183; FRANK CHAU, Reg. No. 34,136; CHRISTOPHER G. TRAINOR, Reg. No. 39,517; GEORGE LIKOUREZOS, Reg. No. 40,067; JAMES M. LOEFFLER, Reg. No. 37,873; WILLIAM E. LEWIS, Reg. No. 39,274; JOHN G. TUTUNJIAN, Reg. No. 39,405; JAMES J. BITETTO, Reg. No. 40,513; and MARK S. LEONARDO, Reg. No. 41,433, each of them of DILWORTH & BARRESE, 333 Earle Ovington Boulevard, Uniondale, New York 11553.

Send correspondence to:

John C. Andres
Chief Patent Counsel
Legal Department
UNITED STATES SURGICAL CORPORATION
150 Glover Avenue
Norwalk, CT 06856

Direct telephone calls to:

Neil D. Gershon
203-845-1480

Dated: 3/9/98

VALLEYLAB INC

By: 

Richard Granger
President